DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Fort Dodge Animal Health, Division of Wyeth. The ANADA provides for use of three different strength trenbolone acetate and estradiol implants in cattle.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 500 Fifth St. NW., Fort Dodge, IA 50501, filed ANADA 200–367 for the use of three different strength trenbolone acetate and estradiol implants in cattle. SYNOVEX T120 and SYNOVEX T80 are for use in steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. SYNOVEX T40 is for use in pasture cattle (slaughter, stocker, and feeder steers and heifers) for increased rate of weight gain. Fort Dodge Animal Health's SYNOVEX T120, SYNOVEX T80, and SYNOVEX T40 are approved as generic

copies of Intervet, Inc.'s REVALOR–S, REVALOR–IS, and REVALOR–G, approved under NADA 140–897. The application is approved as of November 18, 2003, and the regulations are amended in 21 CFR 522.2477 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.2477 is amended by adding paragraph (b)(3) and by revising the heading of paragraph (d)(3) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(b) * * *

(3) No. 000856 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii).

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(d) * * *

(3) *Pasture cattle (slaughter, stocker, and feeder steers and heifers)*—* * *

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Dated: December 23, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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